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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,942	06/02/2000	Daniel Flammang	39558/DBP/E43	6577

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/22/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/586,942

Applicant(s)

FLAMMANG, DANIEL

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/10/03 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102/ 35 USC § 103

1. Claims 14 and 19-24 and 26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McGee et al. (US 5855592) in view of Ljungstrom (EP 0 601 328 A 1) and further in view of Altman et al. (US 4726379).

As to claim 20, Mc Gee et al. disclose a multi-site cardiac defibrillation system comprising an electrode arrangement (10) having a lead (12) with an undivided proximal end (14), a distal end (16) and an electrode support assembly (20) with spline elements (22) (branches) (col. 5 @ 66 – col. 6 @ 10). In the figure 6 embodiment, an electrical pulse-discharging device (58) is connected to one or more arrays of electrodes (70), each array having a splitter (72) and branches (67) with a central core structure made of memory wire (a memory member structure). Eight electrodes (67) are disposed on each branch (col. 14 @ 29-61). The number of branches can be eight or fewer, read to be two branches (col. 6 @ 32-36). The characteristic of “unambiguously associated” electrodes is accepted to be electrodes from different lead branches grouped to stimulate a defined area. If the plurality of electrodes is read as two electrodes, each branch has a single electrode, hence creating a single region where the two electrodes are unambiguously associated (col. 3 @ 13-20; col. 4 @ 13-19). If the plurality of electrodes is read as to be an even number of electrodes, each branch has an equal number of electrodes and the electrodes on the first and second branches create a pair of unambiguously associated electrodes, hence creating bands/ regions of stimulated myocardium (col. 7 @ 60-64; col. 8 @ 15-21; col. 9 @ 60-65). Note that the concept of contacting the “lateral and septal”

regions amounts to an intended use limitation of which McGee is inherently capable of performing.

As to claim 14, the slidable sheath (44) (sliding sleeve) is deployed by adjusting the sheath using a rearward movement (arrow 43) (figures 3 and 4; col. 6 @ 37-63).

As to claim 18, the memory member structure contains titanium (col. 6 @ 8-10).

As to claim 19, the electrode arrangement has three different branches (figure 6).

As to claim 21, the branches each contain eight electrodes (about seven electrically conductive surface portions) (figure 6).

As to claims 22 and 23, the conductive surface portion are ring electrodes, one ring electrode located at the distal end of each branch (col. 14 @ 45-48).

As to claim 24, the electrodes are spaced one centimeter apart (col. 9 @ 53-55).

As noted above, the number of branches can be eight or fewer, read to be two branches, the lateral and septal branches (col. 6 @ 32-36).

As to the conductive surface portions/ electrodes being unambiguously associated in pairs, McGee et al. teach delivering pacing to bands/ stimulation layers using electrodes on the spline elements (col. 9 @ 60-65). If the configuration has only two spline elements each having a single electrode in the individual bands (col. 9 @ 65 - col. 10 @ 2), the pacing involves pairs of electrodes (col. 6 @ 34-36). As previously discussed above, the characteristic of "unambiguously associated" electrodes is accepted to be electrodes from different lead branches grouped to stimulate a defined area. If the plurality of electrodes is read as two electrodes, each branch has a single electrode, hence creating a single region where the two electrodes are

Art Unit: 3762

unambiguously associated (col. 3 @13-20; col. 4 @ 13-19). If the plurality of electrodes is read as to be an even number of electrodes, each branch has an equal number of electrodes and the electrodes on the first and second branches create a pair of unambiguously associated electrodes, hence creating bands/ regions of stimulated myocardium (col. 7 @ 60-64; col. 8 @ 15-21; col. 9 @ 60-65).

As to the bipolar mode of operation (claim 20), it is accepted that the distinction between unipolar and bipolar pacing modes reflects the distance between the two electrodes. In the unipolar mode, the anode is remotely located (often accomplished by having the simulator housing located in the patient's thorax serve as the anode) and in the bipolar mode, the anode is located close to the cathode (often accomplished by having both electrodes on lead(s) in the patient's heart, one electrode serving as an anode). It is inherent that McGee et al. teach using a bipolar mode of pacing for most embodiments because the electrodes are located closely together in the heart (figure 6; col. 9 @ 8-18). McGee provides a unipolar pacing mode (col. 9 @ 34-37).

As to using an anode and a cathode (claim 20), it is accepted that when using a pair of electrodes for cardiac stimulation, the negatively charged electrode, the cathode, is the electrode most closely associated with the point of origin of the cardiac stimulation and the positively charged electrode, the anode, is the electrode more remotely associated with the point of cardiac stimulation. It is inherent, McGee et al. teach using a pair of electrodes to serve as an anode and a cathode.

In the alternative, given that McGee et al. do not explicitly call for lateral and septal branches, Ljungstrom teaches electrode arrangements using a two limb-shaped structure to uniformly distribute the conductors over the electrode head for the purpose of providing a comparatively large defibrillation area. Based on the location of the limbs/ branches in figure 4, the two branches are named the septal branch (19) and the lateral branch (18). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the McGee branches in the septal and lateral areas of the heart in order to uniformly distribute the electrodes over the atrium providing optimal atrial tissue stimulation (figure 4; page 3 @ 5-11).

In the alternative, given that McGee et al. do not explicitly call for a bipolar pacing mode using an anode and a cathode, Altman teaches that a bipolar mode of operation occurs when both electrodes are located in the heart, rather than one electrode being located remotely. Altman also teaches when a pair of electrodes is used to pace or sense cardiac activity, one electrode serves as an anode and the other electrode serves as a cathode. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the terms bipolar mode of operation and anode and cathode in association with the McGee et al. system in order to use terms known in the art to define the pacing configuration where the both electrodes are located in the heart, one serving as an anode and the other serving as a cathode (col. 1 @ 42-57).

Art Unit: 3762

The Applicant's arguments filed 6/10/03 have been fully considered but they are not convincing.

In response to the Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to the Applicant's argument that the references fail to show a certain feature of the Applicant's invention, it is noted that the feature upon which the Applicant relies (i.e., dividing the cardiac tissue resulting in a better defibrillation device) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicant asserts by implication that McGee et al. only teach applying single paces from different electrodes at different times, hence the claimed invention is not disclosed. The Examiner disagrees. As previously discussed, if the plurality of electrodes is read as to be an even number of electrodes, each branch has an equal number of electrodes and the electrodes on the first and second branches create a pair of unambiguously associated electrodes, hence creating bands/ regions of stimulated myocardium (col. 7 @ 60-64; col. 8 @ 15-21; col. 9 @ 60-65). As disclosed by McGee et al, the electrodes can be paced individually, as a pair, or as a larger group (col. 8 @ 15-21; col. 9 @ 8-11 and 60-65).

2. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGee et al. (US 5855592) in view of Cookston et al. (US 5834031), or in the alternative, under 35 U.S.C. 103(a) as obvious over McGee et al. (US 5855592) in view of Ljungstrom (EP 0 601 328 A 1) and further in view of Altman et al. (US 4726379) and further in view of Cookston et al. (US 5834031). As discussed in paragraph 1 of this action, McGee et al./modified McGee et al. disclose the claimed invention except for a means for heating the memory member structure.

Cookstone et al. teach lead placement using ohmic heating for the purpose of deflecting the memory member in the lead to enhance electrode contact with a desired heart region. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used ohmic heating in the McGee et al./ modified McGee et al. system in order to effect proper lead contact and to avoid excessive lead implantation cost associate with lead damage and increased operating time (figures 4-6: col. 1 @ 7-20 and 28-31; col. 2 @ 11-39; col. 3 @ 31-45; col. 7 @ 3-65).

3. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGee et al. (US 5855592) in view of Hess (US 4664120), or in the alternative, under 35 U.S.C. 103(a) as obvious over McGee et al. (US 5855592) in view of Ljungstrom (EP 0 601 328 A 1) and further in view of Altman et al. (US 4726379) and further in view of Hess (US 4664120). As discussed in paragraph 1 of this action, McGee et al./ modified McGee et al. disclose the claimed invention except for the lead configuration including two branches and a ventricular branch with at least one ventricular electrode.

Hess teaches multifunctional lead design using a configuration including two branches and a ventricular branch with at least one ventricular electrode for the purpose of establishing and maintaining reliable contact with portions of the heart undergoing testing and/ or treatment. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a lead configuration including two branches and a ventricular branch with at least one ventricular electrode in the McGee et al./ modified McGee et al. system in order to effectively and efficiently perform multiple functions, such as mapping or pacing, in connection the diagnosing or treatment of cardiac conditions (col. 1 @ 7-13; col. 2 @ 21-31; figures 4 and 5).

Statutory Basis

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 3762

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
7/16/03

Angela D. Sykes

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